EXHIBIT H

Clinical Expert Report

Laser Cut Mesh for

GYNECARE TVT * Tension-free Support for Incontinence

GYNECARE TVT* Tension-free Support for Incontinence with Abdominal Guides

GYNECARE TVT Obturator* System Tension-free Support for Incontinence

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1. SCOPE

This project scope applies to PROLENE* mesh laser cutting. It may be applied to the following TVT products:

810041A – GYNECARE TVT with Abdominal Guide (single use device)
810041B – GYNECARE TVT Blue (single use device), 1-up
830041 – GYNECARE TVT Clear, 3-up
830041B – GYNECARE TVT Blue, 3-up
810081 – GYNECARE TVT Obturator System (single use device)

There will be no other changes to the product, process or biocompatibility of the product and the indications for use will remain the same.

2. BACKGROUND

The need for switching from mechanically cut to laser cut mesh arose as a response to customer needs. Customers expressed a desire for a TVT mesh with smoother edges rather than edges with the ends of individual fibers exposed. Customer feedback also indicated that there was some dissatisfaction with the potential fraying effect of mechanically cut mesh.

3. PRE-CLINICAL EVIDENCE

In order to assure that changing from Mechanically cut to Laser cut mesh would not result in an adverse clinical impact preclinical investigations were undertaken. These investigations were performed to ensure that there were no clinically significant changes in the properties of the mesh resulting from process modifications. These studies compared elongation, flexural rigidity and particle loss properties of laser-cut versus Mechanically-cut Prolene Mesh:

These investigations concluded that:

The elongation analysis determined that each of the two methods of cutting produces meshes have statistically the same properties of elongation within approximately the first 4.0% to 5.0% elongation of the mesh, based on the selected cutting parameters.[1,2]

Flexural Rigidity was slightly higher for the Mechanically cut mesh versus the Laser Cut mesh in the machine direction. The rigidity of the Mechanically cut and Laser cut for the samples in the cross direction was similar[3] This should result in no clinical differences in this respect

Certainly, the variation in tape tensioning seen from one surgeon to another and from one product to another far exceeds any differences seen between

mechanically cut mesh and laser cut mesh as regards elongation characteristics or flexural rigidity.

On average, the Mechanically Cut mesh lost approximately twice the number of particles as the Laser Cut mesh.[3] This demonstrates an advantage of the laser cut material with regard to satisfying the customer need to create a device with less potential for particle loss.

A study was also performed to compare the pull-out force needed to remove the mesh from an animal model mimicking clinical circumstances. In this study, ultrasound cut mesh was compared to mechanically cut mesh. The clinical parameters investigated mesh retention force within the tissue, between 15 minutes and 14 days; tissue in-growth; tissue histology; and failure modes upon removal.[4]

Note that this study was performed on ultrasound cut mesh and not laser cut mesh, however the results can be extrapolated to apply to laser cut mesh based on the following rationale:

The processes of laser cutting and ultrasonically cutting PROLENE mesh both result in heating and melting of the mesh edges. This results in a discrete configuration of the melted edge or what is commonly referred to as the "bead." The bead consists of the melted polymer congealed on the most distal aspects of the filaments. It is defined by the size of the droplet, the connection if any to adjacent droplets, the position of the actual placement of the cut. As long as the beads for the laser cut and ultrasonic cut meshes are the same then the physical properties will be the same: elongation curve profile; maximum force to break; flexibility; particulate loss at 50% elongation; and mesh integrity at 50% elongation, that is, how well the knitted construction holds together. Additionally, when the beads are the same then there should be no clinical difference between the two types of cutting.

To validate the similarity of bead characteristics between the laser and the ultrasonically cut meshes, 4 strips of laser cut (LC) TVT mesh, each approximately 20 ins. in length were evaluated and compared to ultrasonic cut (UC) mesh which was tested during the Ultrasonic Slitting of TVT mesh project. The meshes were viewed under a microscope and the beads that formed on the ends of the filaments at the edges of the mesh strip were evaluated[4,5]

Evaluations of the consistency of the bead size and shape, the position of the bead within the wale of the mesh and whether the beads flowed into the preceding filaments binding them together were also performed. The beads on the LC mesh were very similar in size, position and consistency to the beads on the UC mesh with some exceptions. In certain areas the LC mesh beads were shaped like discs as compared to the UC beads, which were always more like droplets. Additionally, the end filaments of one knot were melted together with

the filaments of the proceeding knot more often with the LC process than with the UC process. These differences should have no clinical impact.

Elongation properties, measuring how many beads broke at 25% and then 50% elongation were also performed, again in comparison to the ultrasonic cut mesh. When pulling on the mesh to elongate it, the beads for both mesh samples either broke or pulled through the loops of the knitted mesh at about the same rate.

In conclusion it is expected that the Laser Cut and Ultrasonically cut samples will function the same in a clinical setting.

4. CLINICAL INTERPRETATION OF PRECLINICAL STUDIES

The slightly higher average elongation of the Mechanically cut mesh at maximum load is not of clinical significance considering that the difference was small and that it is not expected that the mesh will ever approach maximum load in clinical use.

In a recent study by Alex Tong Long Lin et al,the tension sustained by a urethral fascial sling used for SUI during a strong cough in live patients was measured. The results of the study disclosed that the highest average force recorded directly under the mid-urethra was approximately .0485 kg [6]. This occurred in a relatively empty bladder and the patient in the 20^{o} heads-up position. Plotting the elongation of the TVT meshes vs force revealed that at 0.0485 kg (0.5 N) the meshes would elongate approximately 3.8%.

Therefore, in the physiological range at which the meshes are exposed during periods of high stress, approximately up to 50 grams (0.5 N) the elongation properties of the laser cut mesh and the mechanical cut mesh are the same.[1]

The flexural Rigidity of the Mechanically cut mesh was slightly higher than the Laser Cut mesh in the machine direction. The rigidity was similar between the Mechanically cut and Laser cut for the samples in the cross direction. This should not have an impact on clinical functionality and a subjective "feel" evaluation determined that the difference was not readily perceivable. The cross direction flexural rigidity is of no clinical significance because the standard test is not representative to the mesh direction as used in the implant

The decreased particle loss will lead to less non-functioning material left in the tissues.

5. CLINICAL STUDIES

Clinical data was not necessary to establish safety and effectiveness for this change based on the following:

- The indications for use of this device will remain the same.
- Bench top testing showed no physical significant differences between mechanically cut and laser cut mesh within the range of physiologic forces.
- The results of design validation did not raise any new issues of safety or effectiveness

6. CONCLUSIONS AND RECOMMENDATION

The physical properties that might affect clinical performance are essentially the same. It is not anticipated that there will be any clinical differences in the devices that utilize laser cut mesh. Clinical data is not necessary to establish the safety and effectiveness of the devices affected by these changes.

7. REFERENCES

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[2] "Elongation Characteristics of Laser Cut PROLENE Mesh for TVT", G. Kammerer, March 6, 2006

[3] BE-2005-1920 Protocol to Evaluate Elongation, Particle Loss and Flexural Rigidity of TVT U PROLENE Mesh Laser-Cut vs. Mechanical-Cut. The mesh used in this study is identical to the mesh used in the other TVT products.

[4] "Histological Evaluation and comparison of mechanical pull out strength of PROLENE mesh and PROLENE Soft mesh in a rabbit model", PSE Accession No. 02-0579, Project 48010, Feb 28, 2003, N. Cirelli, G. Kammerer, S. Trenka-Benthin, S. Van Lue.

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